



PATENT
Docket No. SU103 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re: Application of Michael J. Precopio

Serial No. 10/519, 372
Filed: 12/23/2004

Examiner: Neil Levy
Art Unit: 1615

Title: METHODS FOR TREATING ECTOPARASITE INFECTIONS ON THE
MAMMALIAN BODY

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REPLY BRIEF TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant's reply brief, in triplicate, is transmitted herewith in accordance with 37

CFR § 1.193 and § 41.41.

Respectfully submitted,

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REPLY BRIEF UNDER 37 C.F.R. § 1.193 AND § 41.41

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This reply brief is in response to the EXAMINER'S ANSWER dated 09/22/2008.

It is noted that the rejection under 35 USC 112 has been withdrawn and hence
will not be discussed in this response.

On pages 4-6 and 16-17, the Examiner refers to the rejection of claims 45-48, 50-
53, and 55-63 under 35 U.S.C. 102 (b) as being anticipated by Gans.

As set forth on pages 18 and 19 of the Appeal Brief, the Gans reference does not teach or suggest any of the following limitations in independent claim 45:

- a) use of an air-impermeable composition;
- b) wherein the composition is formulated so that when applied to the lice, the composition prevents them from obtaining air through their spiracles;
- c) wherein the composition is applied to the infected areas in a quantity sufficient to completely saturate both the hair and the skin in the infected areas; and
- d) wherein the composition is free from any effective pesticidally active compounds other than benzyl alcohol (and nonetheless kills at least most of the lice, nymphs, and eggs in the infected area).

In addition Gans does not teach or suggest the limitations in dependent claims 47-49, 55-59, or 62, as discussed on pages 18 and 19 of the Appeal Brief.

On page 4, last paragraph of the Answer, the Examiner first refers to Gans teaching that 0.5-20% benzyl alcohol as the only active in compositions on hair and skin of people and animals for up to 20 minutes [0107-0108] to kill 100% of ectoparasites, identified as lice and their eggs [0022, 0051].

The Examiner's conclusion that this disclosure contains the teaching that 100% of the ectoparasites are killed is not supported by the statement "...is effective at killing ectoparasites."

How effective ? not disclosed here or supported elsewhere in Gans publication.

In [0022] appears the statement "Some embodiments of the present invention are effective at killing ectoparasites, which are resistant to established insecticidal compositions, such as, for example, malathion, permithrin and lindane or combinations thereof." Which embodiments ? not disclosed here or elsewhere in Gans. Most embodiments that are disclosed and are effective contain other pediculicides. See sections [0014] – [0050], which are all combinations of active ingredients. In sections [0052] – [0076], active ingredients are disclosed, most of which are not benzyl alcohol or phenylethyl alcohol. Also, in the operating Examples [0114] – [0145], none of these Examples used an aralkyl alcohol as the only active ingredient. In Examples 1 – Example 3 only composition II [0115] in Example 1, a composition without an aralkyl alcohol; in Example 2 a composition containing dipentene, alpha-terpineol, pine needle oil, and isopropanol; and composition II again in Example 3 achieved a 100% kill rate.

Hence, it is apparent that only combinations of active ingredients were found to achieve high kill rates, i.e. Gans compositions are not the compositions of the present invention.

With respect to the Examiner's contention that Gans discloses air impermeable carriers [0110, 0113], or carriers free from air, this contention is respectfully submitted to be incorrect.

Nowhere in section [0110] or section [0113] is there any disclosure of air-impermeable carriers or carriers that prevent the lice from obtaining air (claim 45, step A) b), or in fact anywhere else in the Gans publication. The Examiner's assumption that

Serial No. 10/519, 372
Art Unit: 1615

these carriers result in air impermeable compositions or prevent the lice from obtaining air without any disclosures in Gans that final compositions using these carriers provide freedom from air or air-impermeability is an unwarranted assumption, not in any way supported by the disclosures in the Gans publication. Such speculation by the Examiner is respectfully submitted to be an attempt at a hindsight reconstruction of the reference, e.g. to conclude that a gel or presence of polyethylene glycol necessarily provides freedom from air or renders the compositions air-impermeability is unsupported and in fact not correct. See e.g. in Example 1 on page 18 of the present specification that the preparation of the initial gel of Example 1 required that "mixing was slowed to minimize air entrapment." See also Examples 2-9 on pages 18-22 where in each Example slow mixing was continued until the gel was uniform to minimize air entrapment.

The Examiner also contends that "instant claim 52 is seen to define the substantially air impermeable carrier to be a gel." This is not correct as shown by the above discussed Examples where special techniques are required to remove air from otherwise air-containing gels. Claim 52 is just claiming one of the types of compositions falling within the scope of the invention.

Also, as discussed in section [0078], Gans makes it clear that resistance can develop with only one active ingredient, which cannot happen with the present compositions that kill by suffocation. Ectoparasites cannot become resistant to suffocation.

Serial No. 10/519;372
Art Unit: 1615

The fact that Gans is not disclosing air impermeable compositions is also shown by section [0107] which gives a time of about 20 minutes for his benzyl alcohol-containing compositions to kill ectoparasites (what percentage kill rate?). See e.g. Example 15, pages 24-27, especially page 27, lines 1 and 2 of the present specification where two treatments of 10 minutes each of the composition of Example 1, was 100% effective against lice. See also Example 16 on pages 27-30, where two 10 minute treatments with the Example 1 composition were 100% effective against lice.

Also, in Example 17 on pages 30-31, the ovicidal activity against nits (eggs) was 94.9% for the Example 5 composition and 93.1% for the Example 6 composition.

As stated above, the Examiner refers to polyethylene glycol as well as gels to support his contention that Gans discloses air-impermeable compositions. It is not understood or agreed that the presence of polyethylene glycol automatically confers air-impermeability to compositions, nor does the Examiner explain why or provide evidence that this would necessarily be so.

Hence, it is respectfully contended that Gans nowhere including his Examples, contains a disclosure or requirement of air-impermeability for his compositions, or that they are free from air (step A) b)).

The Examiner refers to disclosures in Gans that benzyl alcohol can be used alone, i.e. a disclosure of step A) e) of claim 45. These disclosures are not disclosures of compositions that fall within the limitations in claim 45, of step A) – substantially air-impermeable compositions, A) b) – formulated to prevent lice from obtaining air through

Serial No. 10/519, 372
Art Unit: 1615

their spiracles, A) c) the critical limitation as shown in the 132 Declaration that complete saturation of the hair and skin, including the entire length of long hairs, is necessary to get highly effective results, and step B) where most of the lice, nymphs and nits have been killed.

On page 5 of the Answer, the Examiner refers to section [0084] as showing that an 80-100% kill rate is obtained for ectoparasites and their eggs. It is respectfully contended that this section does not support the broad statement assumed by the Examiner.

Section [0084] states that "it is believed that these compositions and/or methods will also kill ectoparasite eggs."

It is believed? This is not a disclosure that there is any scientific support for this belief.

Also, what compositions? What methods? What ectoparasite eggs?

Section [0084] also states that "The present invention encompasses compositions that provide, in a single treatment, at least about 50% kill effect, preferably at least about 80%, more preferably about 100%."

What compositions are included? Gans shows in his Examples that only combinations of active ingredients often include known pediculicides, are effective.

What kill rate in section [0084] applies to what compositions? not disclosed.

Serial No. 10/519, 372
Art Unit: 1615

Also on page 5 of the Answer, the Examiner contends that the instant claims specify no means to determine whether or not nymphs are present and killed.

Example 15, page 25, lines 1-3 refers to nymphs, i.e. the presence of nymphs can easily be determined by those skilled in this art. See also Example 16, lines 21-22 and page 29, lines 4-11 where a method for determining whether or not nymphs are present is set forth.

The Examiner further contends on page 5 of the intent to achieve 100% kill is present and a time period of up to 20 minutes is disclosed.

Nowhere in Gans is a composition disclosed containing benzyl alcohol as the only active agent that achieves anywhere near a 100% kill rate, or indeed any kill rate. The Examiner also admits that there is no disclosure in Gans of the criticality of complete saturation of the skin and hair to achieve high kill rates.

At the bottom of page 5 of the Answer, the Examiner contends that one applying a treatment formulation would make every effort to work a treatment formulation into the scalp and hair.

This contention ignores the finding, supported by the 132 Declaration, that the entire length of long hairs must be treated (since some of the lice rapidly drop down the long hairs when the present compositions are applied to the scalp and hair contiguous to the scalp, i.e. the lice recognize a threat). This was unknown prior to the present invention.

Serial No. 10/519, 372
Art Unit: 1615

A repetition of application applies only to Gans compositions and not necessarily to those of the present invention (last two lines on page 5 – top of page 6 of the Answer).

On page 6 the Examiner admits that Gans “does not explicitly state how death occurs”, and that Gans achieves the same result – no lice.

Gans does not achieve such results with any composition containing only benzyl alcohol as the active component, nor does Gans teach or suggest the use of air-impermeable compositions, nor compositions that prevent lice from obtaining air through their spiracles, nor the criticality of complete saturation of even the long hairs in the infected areas.

It is accordingly respectfully contended that the Examiner is rebuilding the Gans reference in the light of Appellant’s disclosures in order for it to operate in a manner never intended or contemplated by the Gans reference. Ex parte Garrett, POBA (1961) 132 USPQ 514. The reference viewed by itself and not in retrospect, must suggest doing what applicant has done. In re Schaffer (CCPA 1956) 108 USPQ 326, In re Skoll (CCPA 1975) 187 USPQ 481.

It is respectfully contended that the Examiner has not provided a sufficient basis upon which to conclude that one having ordinary skill in the art would have been led to modify the Gans reference to arrive at the claimed invention. In re Newell, 891 F.2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989) In re Laskowski, 871 F.2d 115, 10 USPQ2d 1397 (Fed. Cir. 1989).

Serial No. 10/519,372
Art Unit: 1615

In addition, it is not apparent and the Examiner does not explain why the disclosed processes in the prior art would inherently (necessarily) yield the same product used in the present method claims. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); In re Oelrich, 666 F.2d 578, 212 USPQ 323 (CCPA 1981); In re Wilding, 535 F.2d 631, 190 USPQ 59 (CCPA 1976).

There is data in the specification which reveals that products used in the claimed method exhibit properties (e.g. ability to keep breathing apparatuses from closing and the ability to suffocate ectoparasites) which are not exhibited by those prepared in accordance with any process disclosed in the Gans reference. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281.

The Board's attention is respectfully directed to operating Examples 1-14 where compositions containing benzyl alcohol are set forth, and Examples 15, 16, and 17 where the composition of Examples 1, 2, 5 and 6 were evaluated clinically against lice, nymphs, and/or nits wherein each subject (lice infected) had two 10 minutes treatments one week apart in Examples 15 and 16, resulting in 100% effectiveness; and Example 17 where a single 10 minute treatment against nits resulted in ovicidal activity of 94.9% for the composition of Example 5 and 93.1% for the composition of Example 6.

Serial No. 10/519, 372
Art Unit: 1615

In summary, it is respectfully contended that the Gans reference does not teach or suggest any of the following claim limitations of the presently claimed invention, i.e. Gans does not disclose a method for using compositions to kill ectoparasites, their nymphs and eggs in which:

- a) an air-impermeable composition is employed;
- b) formulated to prevent the ectoparasites from obtaining air through their breathing apparatuses;
- c) complete saturation of both the skin and the hair in the infected area;
- d) freedom from any effective pesticidally active compounds other than the monohydric aralkyl alcohol; and
- e) leaving the composition in contact with the skin and hair until at least most of the ectoparasites, nymphs and eggs have been killed.

In addition, the compositions of the Gans reference do not obtain the following advantages obtained by the methods of the invention:

- a) since the mechanism of action includes suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with other pesticide compositions; and
- b) achieving very high kill rates in short periods of time.

On page 6 of the Answer, the Examiner has rejected claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36, and 45-63 under 35 U.S.C. 103 (a) as unpatentable over Lover 4368207 and Bessette 6974584 and Cardin et al 5288483, in view of Pearlman 6303581.

Serial No. 10/519, 372
Art Unit: 1615

With respect first to the Lover reference, the failure of this reference to teach or suggest the presently claimed invention has been discussed at length on pages 20-26 of the Appeal Brief, and will not be repeated here to avoid redundancy.

It is believed that the discussion of the Lover reference in the Appeal Brief fully answers the Examiner's position concerning the Lover reference on page 7 of the Answer.

It is of course recognized that the Lover reference has been combined with the Pearlman reference, also discussed in the Appeal Brief on page 32 thereof.

As discussed in the Appeal Brief, the Pearlman reference is directed to driable pediculostatic agents that elicit an "immersion reflex" in lice to immobilize them. The pediculostatic agents are then dried to kill at least some of the lice. The driable pediculostatic agents used in Pearlman's invention are "surfactants, lipid materials and alkanols" (col. 10, lines 48-51). The alkanols within the scope of the invention are disclosed in col. 12, lines 58-65, none of which are the monohydric aralkyl alcohols of formula I of the present invention.

Accordingly, the Pearlman reference is respectfully contended to contain no disclosures relevant to the presently claimed invention, and in any event can be combined with the Lover reference only with the use of hindsight. Also, no matter how the teachings of Pearlman are combined with the teachings of Lover, the presently claimed invention still cannot be obtained.

Serial No. 10/519, 372
Art Unit: 1615

The Examiner is taking a drible unrelated pediculostatic agent from the Pearlman reference and combining this with the substantially ineffective benzyl alcohol/phenyl ethanol – containing compositions of the Lover reference, all without any teaching or suggestion in either of these references to do so, and completely out of context, concluding that the present compositions and methods are thereby obtained, which is respectfully submitted to be incorrect for the reasons discussed above. This rejection is contended to be a hindsight rejection using the present invention as a template.

With respect to the Bessette reference, this reference has been discussed in the Appeal Brief on pages 26-28 and will not be repeated here, except as needed to respond to the Examiner's contentions.

On page 7 of the Answer, the Examiner refers to the utilization of benzyl alcohol (column 2, lines 50-57) to result in 100% mortality (column 3, lines 61-67) with or without other toxicants (col. 4, top).

The specifics relating to the broad general statement in col. 2, lines 50-57 must also be considered to understand which compositions are actually effective.

The Bessette reference discloses benzyl alcohol as one of an extensive list of plant essential oils (see col. 3, lines 15-37). A preferred embodiment is a mixture of benzyl alcohol and pyrethrins (see col. 3, lines 39-45).

In the test results given in Example 1, column 7, only benzyl alcohol in combination with pyrethrins (the latter being excluded from the claims) gave "very good kill". Other benzyl alcohol-containing compositions (i.e. compositions G and H

Serial No. 10/519, 372
Art Unit: 1615

containing eugenol, another plant essential oil) (see col. 3, line 26) were rated as less effective than compositions A-D, without any indication as to whether Kill or Repellancy was being measured.

Column 3, lines 61-67 contains another broad statement as to 100% mortality, not supported in the above test results.

Also, col. 3, lines 41-43 only refers to benzyl alcohol as part of mixture of plant essential oils.

The Examples have been discussed above, and benzyl alcohol is never used alone. Also, even where benzyl alcohol is part of a mixture with eugenol, its effectiveness is not highly rated.

Concerning benzyl alcohol being used alone, nowhere in the Bessette reference is this disclosed.

Also, the compositions disclosed by Bessette (see col. 3, line 59- col. 6, line 52) contain no disclosure of air-impermeable compositions, nor compositions that are free from air (nor compositions that kill by suffocation), as required by the present claims.

Furthermore, in col. 4, lines 34-35 appears the statement that "Formulations containing the pesticidal compositions of the present invention may be prepared in any known manner...", i.e. these are conventional formulations. See also Example 1 (col. 6, line 65 – col. 8, line 12) where "The plant essential oils and blends thereof were dissolved in a test solvent and applied to various surfaces" (col. 7, lines 5-7), i.e. no disclosure of compositions that are air-impermeable or prevent ectoparasites from obtaining air. Also,

Serial No. 10/519, 372
Art Unit: 1615

Example 1 is given to test the pesticidal activity of the essential oils, not a disclosure of the presently claimed compositions used in the methods of the invention.

There is no basis for an assumption that Bessette is using air-impermeable carriers or carriers that are free from air, and the Examiner has provided no basis for making any such assumption.

In conclusion, Bessette does not teach or suggest any of the following limitations in the claims:

- a) use of an air-impermeable composition;
- b) wherein the composition is formulated to prevent the ectoparasites from obtaining air through their breathing apparatuses;
- c) applied in a quantity to completely saturate both the hair and skin in the infected areas (see the 132 Declaration);
- d) wherein the composition is free from pesticides other than any pesticidal activity exhibited by the monohydric alcohols (or benzyl alcohol) – the only benzyl alcohol – containing compositions tested by Bessette are combinations of plant essential oils (test compositions A, C, G and H), and most of these are of limited effectiveness.
- e) Leaving the composition until most of the ectoparasites, nymphs, and eggs have been killed. [Please note: this is a more accurate summary than that given on pages 27 and 28 in the Appeal Brief].

Serial No. 10/519, 372
Art Unit: 1615

It is therefore respectfully contended that Bessette does not teach or suggest the presently claimed method of the above claims.

Concerning the Pearlman reference, the "in view of" reference, Pearlman has been discussed above for the Lover reference, and the discussion is equally applicable here as well.

With respect to the Cardin reference, this reference has been discussed on pages 29-32 of the Appeal Brief and will not be repeated here, except as necessary to counter the Examiner's contentions with respect to this reference.

On page 8 of the Answer, the Examiner refers to a teaching in Cardin that conventional pesticides may be added and are not required.

The Examiner concludes from this that the claim requirement of free of other actives is therefore met.

However, this reference discloses ovicidal/pediculicidal anti-lice compositions containing quarternary ammonium salts, long chain fatty amines, and mixtures thereof with alkanol synergizers selected from phenyl C₂-C₆ alkanols, phenyl C₂-C₆ diols, and mixtures thereof.

The alkanols are never used alone, and their only disclosed function is to act as synergizers for the ammonium compounds and amines, which are the chemical pediculicides. See e.g. column 3, lines 21-22, where it is stated that "In the present invention, alkanol synergizers enhance the efficacy of the active compositions", (i.e. the

Serial No. 10/519, 372
Art Unit: 1615

amine/ammonium pesticidally active compounds)(underlining added). See also col. 2, lines 43-45 where it is stated that "Quarternary ammonium salts are disclosed as the lone pediculicide." (underlining added). See further col. 2, lines 43-45 and col. 7, lines 44-45, where it is stated that "Cationic surfactants, disclosed above as having anti-lice activity..." (underlining added).

All of the above claims on appeal contain the limitation that no pesticides are present in the compositions used in the method of the invention other than any pesticidal activity provided by the monohydric aralkyl alcohols, hence excluding all of the compositions of Cardin, in which the ammonium compounds and amines are chemical pediculicides (see e.g. col. 3 above and col. 2, lines 43-45). Cardin requires the presence of quarternary ammonium/amine pesticides.

The Examiner refers to a disclosure that "conventional pesticides" may be added (col. 6, lines 22-25). This is a disclosure that other pesticides may be added, e.g. pyrethrins, in addition to the amine/ammonium pediculicides which are always present.

As discussed above, there is no question that the amine/ammonium compounds are pediculicides. See e.g. col. 3, lines 21-22 where it is stated that "In the present invention, alkanol synergizers enhance the efficiency of the active compositions" (i.e. the amine/ammonium compounds).

In conclusion, Cardin does not teach or suggest the following limitations and advantages:

- a) air-impermeable compositions;

- b) in amount sufficient to prevent the ectoparasites from obtaining air through their breathing apparatuses;
- c) leaving the compositions in place until at least most of the ectoparasites, nymphs and eggs are killed;
- d) achieving very high kill rates in short periods of time (advantage);
- e) since the mechanism of action includes suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with chemical pesticides (advantage);
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the skin and hair. See the discussion of the 132 DECLARATION in the Appeal Brief.

Concerning the Pearlman reference, Pearlman adds no disclosures to the Cardin reference that teaches or suggests any of the above limitations and advantages, especially without the use of a hindsight reconstruction of the teachings of the Cardin and Pearlman references. See pages 32-34 of the Appeal Brief. As discussed by the Examiner on pages 8-10, Pearlman's compositions do not kill ectoparasites in liquid form – only when dried are at least some of the lice killed, and monohydric aralkyl alcohols are not even disclosed for use in the compositions of the Pearlman reference.

Serial No. 10/519, 372
Art Unit: 1615

It is respectfully contended that the Examiner's attempted reconstruction of the Pearlman, Lover, Bessette and Cardin references is based on assumptions nowhere disclosed in any of the references, i.e. a completely hindsight reconstruction.

On page 10 of the Answer, the Examiner contends that only benzyl alcohol has been shown to provide nonobvious or unexpected results.

It is Appellant's expert opinion and contention that other formula I compounds and monohydric aralkyl alcohols will provide similar results to those discovered for benzyl alcohol, and the Examiner has provided no evidence or expert opinion to the contrary.

The Examiner has also contended that Appellant has provided no objective evidence to distinguish the present invention from the prior art. This is simply not true — see the present Examples and discussion of what the prior art does not teach concerning the presently claimed invention.

It is respectfully submitted that the Examiner's arguments on pages 10-12 and 16-17 have been fully contravened in the Appeal Brief and in this Reply Brief, and therefore further discussion would be redundant.

On pages 12-15 of the Answer, the Examiner has set forth several obviousness-type double patenting rejections.

With respect to the rejection over claims of U.S. 6, 793, 931, this rejection has been discussed in detail in pages 37-38 of the Appeal Brief.

Serial No. 10/519, 372
Art Unit: 1615

On pages 12 and 13 of the Answer, the Examiner contends that "one [skilled] in the art would find the nymphs and eggs also pesticidally affected". This contention is respectfully submitted to be incorrect – pesticidal activity is not identical to, nor does it necessarily include, ovicidal activity, and the Examiner does not provide any evidence to the effect that pesticidal activity necessarily includes ovicidal activity.

On page 13 of the Answer, the Examiner states that arguments for complete saturation, except time of application, is undefined. This contention is not understood – the 132 Declaration shows the importance of making certain that even the long hairs must be properly treated with the present composition, since the lice, which normally are at or near the scalp, recognize a threat and rapidly climb down the long hairs. This was an unexpected discovery, not in any way obvious from the claims in the '931 patent.

In conclusion, it is submitted that the limitations in the '931 patent claims do not render obvious the following limitations in independent claims 1 and 45:

1. Effectiveness against ectoparasite nymphs and eggs as well as the ectoparasites themselves. The fact that compositions are found to be effective against ectoparasites does not mean that they are also effective against ectoparasite eggs.
2. The requirement of complete saturation of the hair and skin. The importance and unobviousness of this has been demonstrated in the 37 CFR § 132 DECLARATION included with the Appeal Brief, and

Serial No. 10/519, 372
Art Unit: 1615

discussed above and in the Appeal Brief. It is again respectfully contended that this was an unobvious discovery and nothing in the '931 claims render this limitation obvious.

3. Leaving the composition in contact with the infected skin and hair until most of the nymphs and eggs have been killed (as well as the ectoparasites). There is nothing in the claims of the '931 patent that would render this limitation concerning ectoparasite eggs obvious.

In addition, claim 1 also includes the following limitation:

4. The present claims are directed to the topical treatment of ectoparasites (not just lice). The claims of the '931 patent are limited to the treatment of lice and it is therefore not obvious from the claims that the compositions can include the treatment of ectoparasites other than lice.

At the bottom of page 13 of the Answer, the Examiner rejects claim 1 and most of the claims dependent thereon over a number of claims in SN 10/382, 188.

This provisional rejection has been discussed on page 39 in the Appeal Brief.

The Examiner presents arguments on pages 14-15 of the Answer. Included in these arguments are arguments with respect to independent claim 45 in the present application. However, arguments with respect to claim 45 are irrelevant since claim 45 has not been included in the rejection.

Serial No. 10/519, 372
Art Unit: 1615

With respect to the arguments for obviousness for present claim 1, these arguments are not directed to the following limitations in present claim 1, set forth on page 39 of the Appeal Brief:

1. The requirement of complete saturation of the hair and skin. The importance and unobviousness of this has been demonstrated in the 37 CFR § 132 DECLARATION included with the Appeal Brief, and discussed above. It is respectfully contended that this was an unobvious discovery and nothing in the '188 claims render this limitation obvious.
2. The present claims are directed to the topical treatment of ectoparasites (not just lice). The claims of the '188 application are all limited to the treatment of lice and it is therefore not obvious from these claims that the compositions can include the treatment of ectoparasites other than lice.

On page 15 of the Answer, the Examiner presents arguments for an obviousness-type rejection of claim 1 and claims dependent thereon over claims of U.S. 7, 294, 342.

At the bottom of page 15 of the Answer, the Examiner argues that the limitation of "complete saturation" is unspecified in the claims. This argument has been discussed above with respect to the rejection over claims of U.S. 6, 793, 931, and the discussion is equally applicable here.

The Examiner contends further that a 70% kill still meets the instant claim to providing pesticidal activity.

Serial No. 10/519, 372
Art Unit: 1615

The 132 Declaration shows that a 100% treatment success and a kill rate greater than 99% was obtained when complete saturation of the entire length of each subject's hair was utilized. This difference in results was surprising and unexpected.

Accordingly, it is again contended that the patented claims, do not contain at least the following limitations in claim 1, which limitations are not obvious from the '342 claims:

1. Effectiveness against ectoparasite nymphs and eggs as well as the ectoparasites themselves. The fact that compositions are found to be effective against ectoparasites does not mean that they are also effective against ectoparasite eggs.
2. The requirement of complete saturation of the hair and skin. The importance and unobviousness of this has been demonstrated in the 37 CFR § 132 DECLARATION included with the Appeal Brief, and discussed above. It is respectfully contended that this was an unobvious discovery and nothing in the '342 claims render this limitation obvious.
3. Leaving the composition in contact with the infected skin and hair until most of the nymphs and eggs have been killed (as well as the ectoparasites). There is nothing in the claims of the '342 patent that would render this limitation concerning ectoparasite eggs obvious.

Serial No. 10/519, 372
Art Unit: 1615

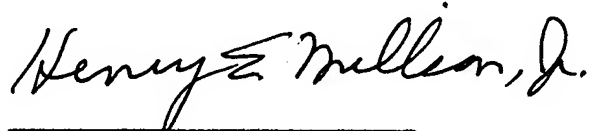
4. The present claims are directed to the topical treatment of ectoparasites (not just lice). The claims of the '342 patent are limited to the treatment of lice and it is therefore not obvious from the claims that the compositions can include the treatment of ectoparasites other than lice.

On pages 16 and 17 of the Answer, the Examiner presents responses to Appellant's arguments.

As discussed above, it is respectfully contended that the Examiner's responses have been fully argued in the Appeal Brief and this Reply Brief, and further discussion would be redundant.

Accordingly, the Board is respectfully requested to find for Appellant with respect to the patentability of all of the claims on appeal.

Respectfully submitted,



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